Calendar No. 587

111TH CONGRESS
2D SESSION

S. 3751

To amend the Stem Cell Therapeutic and Research Act of 2005.

IN THE SENATE OF THE UNITED STATES

AUGUST 5, 2010

Mr. HATCH (for himself, Mr. DODD, Mr. BURR, Mr. REED, Mr. ENSIGN, Mr. FRANKEN, Mrs. HAGAN, Ms. KLOBUCHAR, and Mr. COBURN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

SEPTEMBER 23, 2010

Reported by Mr. HARKIN, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To amend the Stem Cell Therapeutic and Research Act of 2005.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

~~**SECTION 1. SHORT TITLE.**~~

~~This Act may be cited as the "Stem Cell Therapeutic and Research Reauthorization Act of 2010".~~

SEC. 2. AMENDMENTS TO THE STEM CELL THERAPEUTIC AND RESEARCH ACT OF 2005.

(a) CORD BLOOD INVENTORY.—Section 2 of the Stem Cell Therapeutic and Research Act of 2005 (42 U.S.C. 274k note) is amended—

(1) in subsection (a), by inserting ''at least'' before ''150,000'';

(2) in subsection (c)(3), by inserting ''at least'' before ''150,000'';

(3) in subsection (d)—

(A) in paragraph (2), by striking ''; and'' and inserting '';'';

(B) by redesignating paragraph (3) as paragraph (5); and

(C) by inserting after paragraph (2) the following:

''(3) will provide a plan to increase cord blood unit collections at collection sites that exist at the time of application, assist with the establishment of new collection sites, or contract with new collection sites;

''(4) will annually provide to the Secretary a plan for, and demonstrate, ongoing measurable progress toward achieving self-sufficiency of cord blood unit collection and banking operations; and'';

(4) in subsection (e)—

(A) in paragraph (1)—

(i) by striking ''10 years'' and inserting ''a period of at least 10 years beginning on the last date on which the recipient of a contract under this section receives Federal funds under this section''; and

(ii) by striking the second sentence and inserting ''The Secretary shall ensure that no Federal funds shall be obligated under any such contract after the date that is 5 years after the date on which the contract is entered into, except as provided in paragraphs (2) and (3).'';

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A)—

(I) by striking ''Subject to paragraph (1)(B), the'' and inserting ''The''; and

(II) by striking ''3'' and inserting ''5'';

(ii) in subparagraph (A)—

(I) by inserting ''at least'' before ''150,000''; and

(II) by striking ''; and'' and inserting '';'';

(iii) in subparagraph (B)—

(I) by inserting ''meeting the requirements under subsection (d)'' after ''receive an application for a contract under this section''; and

(II) by striking ''or the Secretary'' and all that follows through the period at the end and inserting ''; or''; and

(iv) by adding at the end the following:

''(C) the Secretary determines that the outstanding inventory need cannot be met by the qualified cord blood banks under contract under this section.''; and

(C) by striking paragraph (3) and inserting the following:

''(3) EXTENSION ELIGIBILITY.—A qualified cord blood bank shall be eligible for a 5-year extension of a contract awarded under this section, as described in paragraph (2), provided that the qualified cord blood bank—

''(A) demonstrates a superior ability to satisfy the requirements described in subsection (b) and achieves the overall goals for which the contract was awarded;

''(B) provides a plan for how the qualified cord blood bank will increase cord blood unit collections at collection sites that exist at the time of consideration for such extension of a contract, assist with the establishment of new collection sites, or contract with new collection sites; and

''(C) annually provides to the Secretary a plan for, and demonstrates, ongoing measurable progress toward achieving self-sufficiency of cord blood unit collection and banking operations.'';

(5) in subsection (g)(4), by striking ''or parent''; and

(6) in subsection (h)—

(A) by striking paragraph (2) and inserting the following:

''(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary to carry out the program under this section $23,000,000 for each of fiscal years 2011 through

2014 and $20,000,000 for fiscal year 2015. Such funds so appropriated shall remain available until expended.''; and

(B) in paragraph (3), by striking ''in each of fiscal years 2007 through 2009'' and inserting ''for fiscal years 2011 through 2015''.

(b) NATIONAL PROGRAM.—Section 379 of the Public Health Service Act (42 U.S.C. 274k) is amended—

(1) by striking subsection (a)(6) and inserting the following:

''(6) The Secretary, acting through the Advisory Council, shall submit to Congress an annual report on the activities carried out under this section.'';

(2) by striking subsection (d)(2)(D) and inserting the following:

''(D) support studies and demonstration and outreach projects for the purpose of increasing cord blood unit donation and collection from a genetically diverse population, including exploring novel approaches or incentives, such as remote or other innovative technological advances that could be used to collect cord blood units, to expand the number of cord blood unit collection sites partnering with cord blood

banks that receive a contract under the National Cord Blood Bank Inventory program under section 2 of the Stem Cell Therapeutic and Research Act of 2005;''; and

(3) by striking subsection (f)(5)(A) and inserting the following:

''(A) require the establishment of a system of strict confidentiality to protect the identity and privacy of patients and donors in accordance with Federal and State law; and''.

(c) AUTHORIZATION OF APPROPRIATIONS.—Section 379B of the Public Health Service Act (42 U.S.C. 274m) is amended by striking ''$34,000,000'' and all that follows through the period at the end, and inserting ''$30,000,000 for each of fiscal years 2011 through 2014 and $33,000,000 for fiscal year 2015. Such funds so appropriated shall remain available until expended.''.

(d) REPORT ON CORD BLOOD UNIT DONATION AND COLLECTION.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate, the Committee on Energy and Commerce

and the Committee on Appropriations of the House of Representatives, and the Secretary of Health and Human Services a report reviewing studies, demonstration programs, and outreach efforts for the purpose of increasing cord blood unit donation and collection for the National Cord Blood Inventory to ensure a high-quality and genetically diverse inventory of cord blood units.

(2) CONTENTS.—The report described in paragraph (1) shall include a review of such studies, demonstration programs, and outreach efforts under section 2 of the Stem Cell Therapeutic and Research Act of 2005 (42 U.S.C. 274k note) (as amended by this Act) and section 379 of the Public Health Service Act (42 U.S.C. 274k) (as amended by this Act), including—

(A) a description of the challenges and barriers to expanding the number of cord blood unit collection sites, including cost, the impact of regulatory and administrative requirements, and the capacity of cord blood banks to maintain high-quality units;

(B) remote or other innovative technological advances that could be used to collect cord blood units;

(C) appropriate methods for improving provider education about collecting cord blood units for the national inventory and participation in such collection activities;

(D) estimates of the number of cord blood unit collection sites necessary to meet the outstanding national inventory need and the characteristics of such collection sites that would help increase the genetic diversity and enhance the quality of cord blood units collected;

(E) best practices for establishing and sustaining partnerships for cord blood unit collection at medical facilities with a high number of minority births;

(F) potential and proven incentives to encourage hospitals to become cord blood unit collection sites and partner with cord blood banks participating in the National Cord Blood Inventory under section 2 of the Stem Cell Therapeutic and Research Act of 2005 and to assist cord blood banks in expanding the number of cord blood unit collection sites with which such cord blood banks partner; and

(G) recommendations about methods cord blood banks and collection sites could use to

~~lower costs and improve efficiency of cord blood unit collection without decreasing the quality of the cord blood units collected.~~

SECTION 1. SHORT TITLE.

This Act may be cited as the "Stem Cell Therapeutic and Research Reauthorization Act of 2010".

SEC. 2. AMENDMENTS TO THE STEM CELL THERAPEUTIC AND RESEARCH ACT OF 2005.

(a) CORD BLOOD INVENTORY.—Section 2 of the Stem Cell Therapeutic and Research Act of 2005 (42 U.S.C. 274k note) is amended—

(1) in subsection (a), by inserting "the inventory goal of at least" before "150,000";

(2) in subsection (c)—

(A) in paragraph (2), by striking "or is transferred" and all that follows through the period and inserting "for a first-degree relative."; and

(B) in paragraph (3), by striking "150,000";

(3) in subsection (d)—

(A) in paragraph (1), by inserting "beginning on the last date on which the recipient of a contract under this section receives Federal funds under this section" after "10 years";

(B) in paragraph (2), by striking "; and" and inserting ";";

(C) by redesignating paragraph (3) as paragraph (5); and

(D) by inserting after paragraph (2) the following:

"(3) will provide a plan to increase cord blood unit collections at collection sites that exist at the time of application, assist with the establishment of new collection sites, or contract with new collection sites;

"(4) will annually provide to the Secretary a plan for, and demonstrate, ongoing measurable progress toward achieving self-sufficiency of cord blood unit collection and banking operations; and";

(4) in subsection (e)—

(A) in paragraph (1)—

(i) by striking "10 years" and inserting "a period of at least 10 years beginning on the last date on which the recipient of a contract under this section receives Federal funds under this section"; and

(ii) by striking the second sentence and inserting "The Secretary shall ensure that no Federal funds shall be obligated under

any such contract after the date that is 5 years after the date on which the contract is entered into, except as provided in paragraphs (2) and (3).";

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A)—

(I) by striking "Subject to paragraph (1)(B), the" and inserting "The"; and

(II) by striking "3" and inserting "5";

(ii) in subparagraph (A) by striking "150,000" and all that follows through "and" at the end and inserting "the inventory goal described in subsection (a) has not yet been met;";

(iii) in subparagraph (B)—

(I) by inserting "meeting the requirements under subsection (d)" after "receive an application for a contract under this section"; and

(II) by striking "or the Secretary" and all that follows through the period at the end and inserting "; or"; and

(iv) by adding at the end the following:

"(C) the Secretary determines that the outstanding inventory need cannot be met by the qualified cord blood banks under contract under this section."; and

(C) by striking paragraph (3) and inserting the following:

"(3) EXTENSION ELIGIBILITY.—A qualified cord blood bank shall be eligible for a 5-year extension of a contract awarded under this section, as described in paragraph (2), provided that the qualified cord blood bank—

"(A) demonstrates a superior ability to satisfy the requirements described in subsection (b) and achieves the overall goals for which the contract was awarded;

"(B) provides a plan for how the qualified cord blood bank will increase cord blood unit collections at collection sites that exist at the time of consideration for such extension of a contract, assist with the establishment of new collection sites, or contract with new collection sites; and

"(C) annually provides to the Secretary a plan for, and demonstrates, ongoing measurable

progress toward achieving self-sufficiency of cord blood unit collection and banking operations.";

(5) in subsection (g)(4), by striking "or parent"; and

(6) in subsection (h)—

(A) by striking paragraphs (1) and (2) and inserting the following:

"(1) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary to carry out the program under this section $23,000,000 for each of fiscal years 2011 through 2014 and $20,000,000 for fiscal year 2015.";

(B) by redesignating paragraph (3) as paragraph (2); and

(C) in paragraph (2), as so redesignated, by striking "in each of fiscal years 2007 through 2009" and inserting "for each of fiscal years 2011 through 2015".

(b) NATIONAL PROGRAM.—Section 379 of the Public Health Service Act (42 U.S.C. 274k) is amended—

(1) by striking subsection (a)(6) and inserting the following:

"(6) The Secretary, acting through the Administrator of the Health Resources and Services Adminis-

tration, shall submit to Congress an annual report on the activities carried out under this section.";

(2) in subsection (d)—

(A) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by striking "With respect to cord blood, the Program shall—" and inserting the following:

"(A) IN GENERAL.—With respect to cord blood, the Program shall—";

(ii) by redesignating subparagraphs (A) through (H) as clauses (i) through (viii) respectively;

(iii) by striking clause (iv), as so redesignated, and inserting the following:

"(iv) support and expand new and existing studies and demonstration and outreach projects for the purpose of increasing cord blood unit donation and collection from a genetically diverse population and expanding the number of cord blood unit collection sites partnering with cord blood banks receiving a contract under the National Cord Blood Inventory program under section 2 of the Stem Cell Therapeutic and

Research Act of 2005, including such studies and projects that focus on—

"(I) remote collection of cord blood units, consistent with the requirements under the Program and the National Cord Blood Inventory program goal described in section 2(a) of the Stem Cell Therapeutic and Research Act of 2005; and

"(II) exploring novel approaches or incentives to encourage innovative technological advances that could be used to collect cord blood units, consistent with the requirements under the Program and such National Cord Blood Inventory program goal;"; and

(iv) by adding at the end the following:

"(B) EFFORTS TO INCREASE COLLECTION OF HIGH QUALITY CORD BLOOD UNITS.—In carrying out subparagraph (A)(iv), not later than 1 year after the date of enactment of the Stem Cell Therapeutic and Research Reauthorization Act of 2010 and annually thereafter, the Secretary shall set an annual goal of increasing collections of high quality cord blood units, consistent with

the inventory goal described in section 2(a) of the Stem Cell Therapeutic and Research Act of 2005 (referred to in this subparagraph as the 'inventory goal'), and shall identify at least one project under subparagraph (A)(iv) to replicate and expand nationwide, as appropriate. If the Secretary cannot identify a project as described in the preceding sentence, the Secretary shall submit a plan, not later than 180 days after the date on which the Secretary was required to identify such a project, to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives for expanding remote collection of high quality cord blood units, consistent with the requirements under the National Cord Blood Inventory program under section 2 of the Stem Cell Therapeutic and Research Act of 2005 and the inventory goal. Each such plan shall be made available to the public.

"(C) DEFINITION.—In this paragraph, the term 'remote collection' means the collection of cord blood units at locations that do not have

written contracts with cord blood banks for collection support."; and

(B) in paragraph (3)(A), by striking "(2)(A)" and inserting "(2)(A)(i)"; and

(3) by striking subsection (f)(5)(A) and inserting the following:

"(A) require the establishment of a system of strict confidentiality to protect the identity and privacy of patients and donors in accordance with Federal and State law; and".

(c) ADDITIONAL REPORTS.—

(1) INTERIM REPORT.—In addition to the annual report required under section 379(a)(6) of the Public Health Service Act (42 U.S.C. 274k(a)(6)), the Secretary of Health and Human Services (referred to in this subsection as the "Secretary"), in consultation with the Advisory Council established under such section 379, shall submit to Congress an interim report not later than 180 days after the date of enactment of this Act describing—

(A) the methods to distribute Federal funds to cord blood banks used at the time of submission of the report;

(B) how cord blood banks contract with collection sites for the collection of cord blood units; and

(C) recommendations for improving the methods to distribute Federal funds described in subparagraph (A) in order to encourage the efficient collection of high-quality and diverse cord blood units.

(2) RECOMMENDATIONS.—Not later than 1 year after the date of enactment of this Act, the Advisory Council shall submit recommendations to the Secretary with respect to—

(A) whether models for remote collection of cord blood units should be allowed only with limited, scientifically-justified safety protections; and

(B) whether the Secretary should allow for cord blood unit collection from routine deliveries without temperature or humidity monitoring of delivery rooms in hospitals approved by the Joint Commission.

(d) AUTHORIZATION OF APPROPRIATIONS.—Section 379B of the Public Health Service Act (42 U.S.C. 274m) is amended by striking "$34,000,000" and all that follows through the period at the end, and inserting "$30,000,000

for each of fiscal years 2011 through 2014 and $33,000,000 for fiscal year 2015.".

(e) REPORT ON CORD BLOOD UNIT DONATION AND COLLECTION.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate, the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, and the Secretary of Health and Human Services a report reviewing studies, demonstration programs, and outreach efforts for the purpose of increasing cord blood unit donation and collection for the National Cord Blood Inventory to ensure a high-quality and genetically diverse inventory of cord blood units.

(2) CONTENTS.—The report described in paragraph (1) shall include a review of such studies, demonstration programs, and outreach efforts under section 2 of the Stem Cell Therapeutic and Research Act of 2005 (42 U.S.C. 274k note) (as amended by this Act) and section 379 of the Public Health Service Act

(42 U.S.C. 274k) (as amended by this Act), including—

(A) a description of the challenges and barriers to expanding the number of cord blood unit collection sites, including cost, the cash flow requirements and operations of awarding contracts, the methods by which funds are distributed through contracts, the impact of regulatory and administrative requirements, and the capacity of cord blood banks to maintain high-quality units;

(B) remote collection or other innovative technological advances that could be used to collect cord blood units;

(C) appropriate methods for improving provider education about collecting cord blood units for the national inventory and participation in such collection activities;

(D) estimates of the number of cord blood unit collection sites necessary to meet the outstanding national inventory need and the characteristics of such collection sites that would help increase the genetic diversity and enhance the quality of cord blood units collected;

(E) best practices for establishing and sustaining partnerships for cord blood unit collection at medical facilities with a high number of minority births;

(F) potential and proven incentives to encourage hospitals to become cord blood unit collection sites and partner with cord blood banks participating in the National Cord Blood Inventory under section 2 of the Stem Cell Therapeutic and Research Act of 2005 and to assist cord blood banks in expanding the number of cord blood unit collection sites with which such cord blood banks partner;

(G) recommendations about methods cord blood banks and collection sites could use to lower costs and improve efficiency of cord blood unit collection without decreasing the quality of the cord blood units collected; and

(H) a description of the methods used prior to the date of enactment of this Act to distribute funds to cord blood banks and recommendations for how to improve such methods to encourage the efficient collection of high-quality and diverse cord blood units, consistent with the requirements of the C.W. Bill Young Cell Transplan-

tation Program and the National Cord Blood Inventory program under section 2 of the Stem Cell Therapeutic and Research Act of 2005.

(f) DEFINITION.—In this Act, the term "remote collection" has the meaning given such term in section 379(d)(2)(C) of the Public Health Service Act.

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A BILL

To amend the Stem Cell Therapeutic and Research Act of 2005.

SEPTEMBER 23, 2010

Reported with an amendment